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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,960	11/21/2001	Jeffrey A. Hall	HRT-55405	2916

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FULWIDER PATTON LEE & UTECHT, LLP  
HOWARD HUGHES CENTER  
6060 CENTER DRIVE  
TENTH FLOOR  
LOS ANGELES, CA 90045

EXAMINER
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VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

12

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/990,960

Applicant(s)

HALL, JEFFREY A.

Examiner

Peter J Vrettakos

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35 is/are allowed.
- 6) ☒ Claim(s) 20-27, 34, and 36-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The action is final.

The Applicant has cancelled claims 28-33. Claims 1-19 are withdrawn.

Claims 20-27 and 34-37 are addressed below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 20-22, 26-27, 34, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strul in view of Gentelia et al. and further in view of Marchosky et al. ('422).

#### Independent claim 20

Strul et al. (Strul) discloses an ablation system comprising: a power control system (18, fig. 4), a patient return electrode (23, col. 5:27-31), a computer with a RS-232 data port (col. 7:19-21), an EP monitoring system (ECG, col. 7:12-14), and a processor (60).

Note column 7 lines 26-35. The functions of the processor include *continuous monitoring* (or ongoing verifications) of current and voltage, which provides insight into the connection between the power control system and the return electrode, as well as

the return electrode and the biological tissue. Also, note Strul's disclosure regarding system verification checks in: the last line of the abstract and column 6: 37-42.

Dependent claims

Re: claims 21, 22, and 37, Strul discloses displays (42) and switches (44) that generate error indications when an open circuit in the ablation system is detected (col. 6:37-46). An open circuit could be due to the absence of an inserted connector breaching the connection between the power control system and the patient return electrode.

Re: claims 26-27, and 34, Strul discloses a connector to permit connection of the internal microprocessor to an external computer (col. 7:15-20). Strul discloses, as mentioned above, that when system connections are breached, an error signal is generated. This would inherently include the connection between the computer and the power control system.

Re: claims 31-33, Strul discloses a processor that is adapted to begin continuous monitoring / verification upon initiation of a signal from a switch (44e, col. 6:58-67). Further, Strul discloses a catheter (12) and a catheter receptacle (50).

Note: the applicant's system claims include language directed toward intended use (ex. claim 30, "wait for confirmation that the signals were displayed..."). The examiner is not obligated to provide prior art that explicitly discloses analogous intended use. As long as *all claimed structural elements* are located in the prior art, regardless if

the art mentions analogous intended use, the prior art rejection is valid as the patented invention is deemed *capable* of performing the intended use steps found in the applicant's claims. In other words, the limitations found in the applicant's system claims that are directed toward intended use are not given any weight with regards to prior art rejections throughout this office action.

*Strul, however neglects to explicitly disclose a processor programmed to prevent RF power output when contact between the return electrode and the patient is breached.*

Gentelia discloses a return path monitoring system for use with an ablation system such as that disclosed by Strul comprising, *inter alia*, a monitoring means (processor) that prevents RF power output when contact between the return electrode and the patient is breached (col. 2:34-39.)

*Strul, however also neglects to explicitly disclose a processor programmed to prevent RF power output when contact between the power control system and the computer as well as the EP monitoring system is breached.*

Marchosky et al. (Marchosky) discloses an analogous power control system (col. 17:48, "pHS" including 302,304) in which programming (software) is disclosed (col. 13:13-47) that verifies several system connections that would include those between a

power control system (302) and a computer (314, fig. 8), and a power control system (302) and an EP monitoring system (318, 306, fig. 8). Note col. 17 44-69 through col. 18:1-17, specifically, col. 18:1-5 toward an ECS (302) "safety check."

Further, col. 13:39-42 discloses that when a failure (disconnect) is sensed, power is removed from the system (output of power is prevented).

**Regarding claim 36, Marchosky discloses troubleshooting in col. 34:43-60.**

Therefore, at the time of the invention it would have been obvious to modify Strul in view of Gentelia and further in view of Marchosky by including a processor programmed to prevent RF power output when contact between the return electrode and the patient, the power control system and the computer, and the power control system and the EP monitoring system is breached in order to prevent burns and sub-optimal system performance.

2. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strul in view of Gentelia and further in view of Marchosky et al. and further in view of Newton et al. ('276).

*Strul, Gentelia, and Marchosky neglect to disclose a return electrode with at least two return pads.*

Newton et al. (Newton) discloses a return electrode monitoring system comprising, *inter alia*, a power control system (10), an electrode (16) to be used in a catheter, and two electrically isolated return pads (20,22). Newton also discloses impedance detection circuitry (42) that will generate an error indication when the detected values are not within a targeted range (col. 4:43-53)

Further regarding impedance measurements, Strul discloses continuous monitoring (verification, comparison) of impedance values. When the monitored impedance values are greater than expected, an error indication is generated (col. 6:37-46).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Strul in view of Gentelia and further in view of Marchosky and further in view of Newton by including as a design expedient, two return electrode pads. The motivation would be to avoid three common dangers inherent to single return electrode pads as disclosed by Newton in column 1. Specifically, the use of two pads allows for monitoring of impedance between the return electrodes and the patient itself (in addition to the impedance of the patient return circuit).

### ***Response to Arguments***

Applicant's arguments filed 2-19-04 have been fully considered but they are not persuasive. The Applicant's amendments and arguments are toward intended use of the device. As a result, these arguments would be persuasive if prosecution involved

method claims. However, because the rejections above are toward system claims, the arguments are ineffective.

The Applicant's claims that the prior art does not "disclose the initiation of processor verification through the insertion of a catheter in a catheter receptacle." Regardless if the statement is accurate, the language is toward intended use. It reads as though it belongs in a method claim. Valid rejections toward system claims rely on structural equivalence in the patent and the application. Intended use (ex. a method step) such as initiation of processor verification through the insertion of a catheter in a catheter receptacle is not relevant in the rejection of system claims.

The Applicant's claims that the prior art does not "verify the presence of appropriate software in the computer as a prerequisite to the output of ablation power." Regardless if the statement is accurate, the language is toward intended use. It reads as though it belongs in a method claim. Valid rejections toward system claims rely on structural equivalence in the patent and the application. Intended use (ex. a method step) such as initiation of processor verification through the insertion of a catheter in a catheter receptacle is not relevant in the rejection of system claims.

The Applicant's claims that the prior art does not disclose troubleshooting abilities. However, Marchosky discloses troubleshooting abilities in col. 34:43-60.

The Applicant would most likely find greater success with his presented arguments were the relevant claims toward a method.

***Allowable Subject Matter***



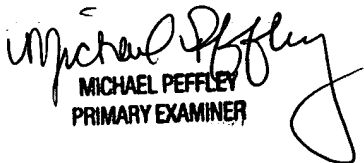
Claim 35 is allowed. The prior art neglects to disclose an ablation system comprising a power control system with a multiple pin EP monitoring system and a processor programmed to display pulses on the EP monitoring system display as a progressive sequence starting with the first pin and ending with the last pin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos  
March 5, 2004

  
MICHAEL PEFFLEY  
PRIMARY EXAMINER